

REMARKS

Claims 1-47 are pending in this application. Claims 1-39 stand rejected. Claims 1, 15 and 22 have been amended. Claim 15 has been amended to insert the citation "and a suitable carrier". Support for amended claim 15 can be found on page 8, lines 16-21 and elsewhere in the specification. Therefore no new matter has been added. Claim 22 has been amended to delete the second occurrence of the term "of vaccine".

New claims 40 to 47 have been added. Support for new claim 40 can be found on page 5, lines 23-29, page 6, lines 18-19, page 19, line 24 to page 23, line 26, Fig. 2, and elsewhere in the specification. Support for new claim 41 can be found on page 5, lines 23-25, page 7, lines 3-12, page 19, line 24 to page 21, line 32, page 23, lines 18-28 to page 25, line 13, Fig. 2 and elsewhere in the specification. Support for new claims 42 to 47 can be found, on page 7, lines 3-12, page 23, lines 18-28 to page 25, line 13, and elsewhere in the specification. Therefore no new matter has been added.

Specification

The Examiner has requested that applicants provide a new title that is clearly indicative of the invention to which the claims are directed. Applicants provide said title with this amendment and response.

The Examiner has requested that applicants update the current status of the priority application by inserting the patent numbers as well as abandoned information. Applicants provide said information with the replacement paragraph of page 1, line 3 to page 1, line 12 in this amendment and response.

Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 1-9, 11-14, 16, 18-25, 27-29, 31-33, 35-37, 39 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, the Examiner stated that it is not clear which regions are forming the chimeric virus.

Applicants have amended independent claim 1. As amended, claim 1, and the claims that depend therefrom, are directed to a recombinant avian herpesvirus comprising a herpesvirus of turkeys unique long and repeat viral genome region that corresponds to nucleotide positions 1 to 136,040 of GenBank accession No. AF291866 and a Marek's disease virus unique short viral genome region that corresponds to nucleotide positions 66 to 11,221 of GenBank accession No. L22174 wherein at least one foreign DNA sequence is inserted within a US2 gene of the unique short region.

Applicants believe the claim 1, as amended, and the claims that depend therefrom, address the Examiner's concern as they now recite specific regions that are disclosed in the applicants' specification. Applicants submit that claim 1, as amended, and the claims that depend therefrom, satisfy the requirements of 35 U.S.C. § 112, second paragraph. Support for the amended claims can be found on page 19, line 24 to page 23, line 26, Fig. 2, and elsewhere in the specification. Therefore no new matter has been added. Accordingly, withdrawal of the rejection under 35 U.S.C. § 112, second paragraph is respectfully requested.

Rejection under 35 U.S.C. § 102

Claims 1-3, 5-7, 9, 11, 13, 18, 20, 24, 25, 28-29, 32-33, 36 and 37 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Cochran *et al.*, US Patent No. 5,965,138 (the '138 patent). Specifically, the rejection states that the product disclosed in the '138 patent appears to be identical or so similar that it is indistinguishable from the product claimed by the applicants (see the claims, and "Example 19").

For the reasons set forth below, applicants respectfully traverse this rejection.

As stated in MPEP § 2131:

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference. Furthermore, the identical invention must be shown in as complete detail as in contained in the ...claim.

The '138 patent refers to a recombinant chimeric virus, a vaccine comprising the chimeric virus and a method of immunizing a bird comprising administering the vaccine. The claimed invention of the present application is not identical to the chimeric virus disclosed in the '138 patent. As amended, claim 1, and the claims that depend therefrom, are directed to a recombinant avian herpesvirus comprising a herpesvirus of turkeys unique long and repeat viral genome region that corresponds to nucleotide positions 1 to 136,040 of GenBank accession No. AF291866 and a Marek's disease virus unique short viral genome region that corresponds to nucleotide positions 66 to 11,221 of GenBank accession No. L22174 wherein at least one foreign DNA sequence is inserted within a US2 gene of the unique short region.

The claimed invention differs from the '138 patent in the following ways: (1) the recombinant avian herpesvirus US2 gene insertion site for foreign DNA, (2) the amount and content of Marek's disease virus (MDV) derived DNA, and (3) the exclusion of MDV repeats from the chimeric virus. In addition, there is no mention of either the MDV US2 gene or the chimeric virus US2 gene in the '138 patent as an insertion site for foreign DNA.

The amount of MDV derived DNA present in the chimeric virus is significantly reduced. The claimed invention of the present application contains approximately 11,155 base pairs of the short region of MDV. This excludes the MDV short repeat regions.

Support for this is found page 19, line 24 to page 23, line 26, Fig. 2, and elsewhere in the present specification. In contrast, the chimeric virus disclosed in the '138 patent contains the

entire MDV short region (29,000 to 33,000 nucleotides). The following citation is from the '138 patent column 37, lines 19-33:

...Cosmid 739-27.16 was constructed by a partial restriction digest with SmaI of MDV DNA and isolation of an approximately 29,000 to 33,000 base pair fragment. The cosmid was constructed utilizing standard recombinant Dna (sic) techniques (Sambrook, et al., 1989) by joining restriction fragments from the following sources. The vector is an approximately 8200 base pair BamHI fragment (made blunt ended with Lenow (sic) DNA (sic) polymerase) from cosmid vector pWE15. The first fragment is an approximately 4050 base pair SmaI K fragment from the short internal repeat region of the MDV viral genome. The second fragment is an approximately 21,000 base pair SmaI B of MDV. The third fragment is an approximately 3,650 base pair SmaI K fragment from the short terminal repeat region of the MDV genome...

More particularly, S-HVY-145 is an example of the chimeric virus disclosed in the '138 patent as shown in Example 19. To construct S-HVY-145, the subgenomic clone 739-27.16 described above that contains a DNA fragment of 29,000 to 33,000 base pairs of the MDV genomic DNA was used. See Example 19 of the '138 patent, column 61, lines 11-29 as follows:

A cosmid was constructed containing the entire (sic) MDV unique short region. MDV genomic DNA (sic) contains several SmaI sites in the unique (sic) long and internal and terminal repeats of the virus but no SmaI sites within the unique short of the virus. The entire unique short region of MDV was isolated by a partial restriction digestion of MDV genomic DNA (sic) with SmaI. A DNA fragment approximately 29,000 to 33,000 base pairs was isolated and cloned into a blunt-ended site of the cosmid vector pWE15. To generate HVY-145, a recombinant HVT/MDV chimeric virus, the cosmid containing the MDV unique short region was combined with cosmids containing the HVT unique long region according to the PROCEDURE FOR GENERATING RECOMBINANT HERPESVIRUS FROM OVERLAPPING SUBGENOMIC FRAGMENTS. The following combinations of subgenomic clones and enzymes were used: 407-32.2C3 with NotI, 172-07.BA2 with BamHI, 407-32.5G6 with NotI, 407-32.1C1 with NotI, and 739-27.16 with NotI.

In summary, the invention disclosed in the '138 patent contains approximately 22,000 more MDV-derived nucleotide sequences than the claimed invention of the present application. Applicants respectfully traverse the above rejection and request reconsideration of claims 1-3, 5-7, 9, 11, 13, 18, 20, 24, 25, 28-29, 32-33, 36 and 37.

Rejection under 35 U.S.C. § 103(a)

Claims 1-39 stand rejected under 35 U.S.C. § 103(a) as being obvious over Cochran *et al.* (United States Patent No. 5,965,138) ("the '138 patent") and Kingham *et al.* (Journal of Virology, May 2001, Vol. 82, 1123-1135).

For the reasons set forth below, this rejection respectfully is traversed.

The '138 patent relates to a recombinant chimeric virus, a recombinant chimeric virus containing a foreign DNA sequence inserted within a non-essential region, a vaccine comprising the chimeric virus and a method of immunizing a bird comprising administering the vaccine.

The rejection states that the '138 patent teaches a recombinant chimeric virus which is a "novel avian virus" by fusing two separate regions of two different yet highly homologous virus to form an expression vector to be employed in expression of foreign antigens to induce an immune response. It was acknowledged that the present vectors now cited are not taught in the '138 patent.

The rejection relied upon Kingham *et al.* as teaching the complete sequence of herpesvirus of turkey (HVT) which includes the US2 region of the virus. The rejection goes on to state that Kingham *et al.* taught the similarity that existed among the HVT and other Marek's disease viruses. It was acknowledged that Kingham *et al.* did not teach a chimeric expression vector.

It was concluded that "it would have been obvious for one of ordinary skill in the art to follow Cochran et al teaching while knowing the exact coordinates provided by Kingham et al to form an expression vector to induce an immune response in birds."

Applicants respectfully point out that a *prima facie* case has not been made. To establish *prima facie* obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the combination of the prior art. MPEP § 2143.03. In addition, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. MPEP § 2143. Put another way, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination or modification. MPEP § 2143.01.

The references cited in the rejection either alone or in combination do not disclose or suggest a recombinant avian herpesvirus comprising a herpesvirus of turkeys unique long and repeat viral genome region that corresponds to nucleotide positions 1 to 136,040 of GenBank accession No. AF291866 and a Marek's disease virus unique short viral genome region that corresponds to nucleotide positions 66 to 11,221 of GenBank accession No. L22174 wherein at least one foreign DNA sequence is inserted within a US2 gene of the unique short region.

Applicants point out for the reasons stated above, the '138 patent does not teach the invention as presently claimed. Independent claim 1 has been amended to now recite specific regions that are disclosed in the applicants' specification. These regions are not taught or suggested by the references for constructing a recombinant avian herpesvirus for the reasons stated above.

For the foregoing reasons, the combination of the '138 patent and the Kingham *et al.* reference do not render claims 1-39 obvious. Accordingly, withdrawal of the rejection of claims 1-39 under 35 U.S.C. § 103(a) over those references is respectfully requested.

CONCLUSION

In view of the above amendments and discussion, reconsideration and withdrawal of these grounds for rejection, and allowance of pending claims 1-47 are respectfully requested.

If the undersigned can be of assistance to the Examiner in addressing issues to advance the application to allowance, please contact the undersigned at the number set forth below.

Respectfully submitted,



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